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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,944	01/26/2006	Shunji Yunoki	TPP31793	8443

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EXAMINER	
KOSSON, ROSANNE	
ART UNIT	PAPER NUMBER
1652	

MAIL DATE	DELIVERY MODE
02/26/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,944	YUNOKI ET AL.	
	Examiner	Art Unit	
	Rosanne Kosson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 17-23* is/are pending in the application.

4a) Of the above claim(s) *19-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,17 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 January 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed on January 22, 2008 has been received and entered. Claims 1-4 and 18-23 have been amended. Claims 5-17 have been canceled. No claims have been added. Claims 19-23 were withdrawn in a previous Office action as being drawn to non-elected inventions. Accordingly, claims 1-4, 17 and 18 are examined on the merits herewith.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Drawings

In view of Applicants' drawings submitted with their response, this objection is withdrawn.

Claim Rejections - 35 USC § 101

In view of Applicants' amendments to the claims, this rejection is withdrawn.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 17 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in

the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

First, claim 1 recites the limitation of a breaking elongation of at least 150%, i.e., a breaking elongation having a lower limit of 150%. This limitation is not found in the specification and is therefore new matter. Page 26, fourth paragraph, recites a breaking elongation of 338%, but that number is not a numerical range with no upper limit. THIS IS A NEW MATTER REJECTION. New matter is prohibited, and Applicants are required to cancel new matter from the claims (see MPEP 608.04).

Second, the limitation of a collagen having a breaking elongation of at least 150% recites a collagen defined only by a functional limitation. The structural properties that yield this functional property are not described in the specification. Thus, one of skill in the art would not know which collagens in the prior art have this functional property. One of skill in the art would not know, in the absence of structural information, whether or not a particular isolated collagen or collagen preparation is encompassed by the claims. The claims recite this genus of collagens without the specification disclosing any species of this genus, apart from the collagen of Example 4. A sufficient written description of a genus of collagens may be achieved by a recitation of structural features common to each member (species) of the genus, **which features constitute a substantial portion of each member of the genus**. The only recited functional feature of the genus in these claims (having a breaking elongation of at least 150%) is not a structural feature and does not constitute a substantial portion of each species in the genus, as the entire structure of the claimed collagens is completely undefined and the specification does not define the structural features necessary for members of the genus to be selected. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Consequently, there is no evidence that a sufficient number of representative species of this large genus were in the possession of the inventors at the time of filing. To satisfy the written description aspect of 35 U.S.C. 112, first paragraph, for a claimed genus of molecules, it must be clear that: (1) the identifying characteristics of the claimed molecules have been disclosed, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these; and (2) a representative number of species within the genus must be disclosed. Because only one species of the claimed genus is disclosed, the claims fail to satisfy the written description requirement.

Claims 1-4, 17 and 18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated stretchable collagen material, does not reasonably provide enablement for an isolated stretchable collagen material having a breaking elongation of 150%. As a result, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether or not undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir.1988). The court in Wands states: “Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is ‘undue,’ not ‘experimentation.’ ” (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. “Whether undue experimentation is needed is not a single, simple factual determination, but rather is a

conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the breadth of the claims, (2) the nature of the invention, (3) the state of the prior art, (4) the relative skill of those in the art, (5) the predictability or unpredictability of the art, (6) the amount or direction or guidance presented, (7) the presence or absence of working examples, and (8) the quantity of experimentation necessary. Although the quantity of experimentation alone is not dispositive in a determination of whether the required experimentation is undue, this factor does play a central role. For example, a very limited quantity of experimentation may be undue in a fledgling art that is unpredictable where no guidance or working examples are provided in the specification and prior art, whereas the same amount of experimentation may not be undue when viewed in light of some guidance or a working example or the experimentation required is in a predictable established art. Conversely, a large quantity of experimentation would require a correspondingly greater quantum of guidance, predictability and skill in the art to overcome classification as undue experimentation. In Wands, the determination that undue experimentation was not required to make the claimed invention was based primarily on the nature of the art, and the probability that the required experimentation would result in successfully obtaining the claimed invention. (Wands, 8 USPQ2d 1406). Thus, a combination of factors which, when viewed together, would provide an artisan of ordinary skill in the art with an expectation of successfully obtaining the claimed invention with additional experimentation would preclude the classification of that experimentation as undue. A combination of Wands factors, which provide a very low likelihood of successfully obtaining the claimed invention with additional experimentation, however, would render the additional experimentation undue.

Factors pertinent to this discussion include the predictability of the art, guidance in the specification, the breadth of claims and the amount of experimentation that would be necessary

to use the invention.

As discussed above, the claims are broad, because they recite the genus of a collagen having a breaking elongation of 150%, without disclosing any species of this genus. The specification does not support the broad scope of the claims.

As discussed above, the specification does not disclose the structural features required to determine whether or not a particular isolated collagen or collagen preparation has a breaking elongation of at least 150%. The specification does not disclose an assay or apparatus that measures the breaking elongation of a particular collagen. Thus, the specification does not provided sufficient guidance to enable the claimed invention.

As discussed below and in Applicants' response, the prior art does not describe collagens by their % breaking elongation. % breaking elongation does not appear to be a conventional parameter that is routinely used to characterize an isolated collagen. The breaking elongation appears to be a physical property that Applicants measured for their collagen preparation. Thus, one of skill in the art would not be able to know whether a particular collagen in the prior art has a breaking elongation that is more than or less than 150%. The instant specification does not allow one of skill in the art to predict this property for a particular prior art collagen.

In the absence of sufficient guidance, obtaining the claimed collagen is unpredictable, and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. Each collagen contemplated for use by one of skill in the art would have to be evaluated on a random make-and-test-for-function basis. Applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166

USPQ 19 24 (CCPA 1970)).

In view of the foregoing, the claims fail to satisfy the enablement requirement.

Claim Rejections - 35 USC § 112, second paragraph

In view of Applicants' amendments to the claims, the rejection in the previous Office action withdrawn.

Claims 1-4, 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the limitation of a breaking elongation of 150%. It is unclear whether the lower limit of this range means that the collagen may be stretched to 2.5 times its original length in a particular direction before it breaks or if it may be stretched to 1.5 its original length. That is, is the extra length to which the collagen may be stretched 150% of the original length or 50%? Clarification and appropriate correction are required.

Claim Rejections - 35 USC § 102

Claims 1-4, 17 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Andre et al. (US 6,541,023), as evidenced by Ohyabu et al. (US 4,275,084) and Jaafar et al. (US 2002/0045848 A1). This rejection and the first two references were discussed in the previous Office action. Neither Andre et al. nor Ohyabu et al. discloses that collagen may be stretched by 150% before it breaks.

Jaafar et al. disclose that collagen is very extensible and breaks at a force of 500 MPa. Elastin can be stretched to 250% of its original length, and elastin, relative to collagen, has a modulus of elasticity that is 20 times lower than that of collagen (see paragraph 3). Thus, if

elastin is less elastic than collagen, but can be stretched to 2 and ½ times its original length, collagen can be stretched to at least 2 and ½ times its original length, and significantly more, for a breaking elongation that is at least 150%.

The specification discloses on p. 27, first paragraph, that Applicants' collagen may be stretched reversibly from 23 mm to 50 mm. But, this stretching does not break, tear or deform the collagen. Thus, this stretching does not appear to be association with a breaking elongation. The fourth paragraph on p. 26 recites that Applicants' collagen has a breaking elongation of 338%, but no lengths or increases in length are given that correspond to this parameter. Consequently, the specification would not have permitted one of ordinary skill in the art at the time of the invention to correlate the degree to which a particular collagen preparation may be stretched before it breaks with a breaking elongation. The collagen of Andre et al. still appears to be the same as the claimed collagen, as a breaking elongation of at least 150% appears to be an inherent property of collagen.

Applicants assert that collagen from the skin is stretchable, collagen from living tissues that is isolated for medical purposes is not stretchable, and the collagen of Andre et al. is not stretchable. Applicants assert that, not only is there a lack of enablement for making the product of the instant invention, but it is not inherent that the collagen of Andre et al. has a breaking elongation of 150%.

In reply, the stretchability of the collagen of Andre et al. is addressed above, and this collagen appears to be as stretchable as that of Applicants. As previously discussed, the collagen of Andre et al. is from fish skin (see col. 2, lines 29-30). Considering the disclosure of Jaafar et al., stretchability, at least to the degree claimed, does appear to be an inherent property of collagen. As for some types of collagen being stretchable and other types not stretchable, Applicants' comment is confusing, as it not clear which types are and are not

stretchable, apart from skin, and it is not clear what, in Applicants' opinion, makes one type stretchable or not stretchable. In any case, the claims do not recite the source or type of collagen used in their composition. The enablement issue is addressed above.

In view of the foregoing, the rejection of record is maintained.

No claim is allowed.

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is (571)272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rosanne Kosson
Examiner, Art Unit 1652

/Elizabeth Slobodyansky, PhD/
Primary Examiner, Art Unit 1652

rk/2008-02-12